

REMARKS

Reconsideration is respectfully requested. Claims 24-27, 29-36 and 38-42 are pending and stand rejected. Claims 24 and 41-42 have been amended. Support for amended claim 24 can be found, for example, on page 12 lines 23-25. New claim 43 has been added. Support for new claim 43 can be found, for example, on page 76 lines 22-39. Claims 1-23, 25-29 and 37 have been cancelled.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Interview Summary

On April 4, 2006, an Examiner Interview was conducted. Examiner Sines and his supervisor Examiner Warden were in attendance. The Applicant was represented by Robin Silva and Jeffery Bernhardt. The Applicant and the Examiners discussed the differences between the present invention and the two primary references: U.S. Patent No. 5,532,128 to Eggers (“Eggers”) and U.S. Patent No. 5,320,808 to Holen *et al.* (“Holen”).

Examiner Warden indicated that the addition of a specific type of detection could render the claims allowable. The detection of current was specifically discussed.

Rejections under 35 USC § 103(a)

The Examiner has rejected claims 24-27, 29-31, 33, 34, 41, and 42 over Eggers in view of Holen. In addition, the Examiner rejects claim 32 over Eggers in view of Holen and further in view of U.S. Patent No. 4,599,303 to Yabusaki (“Yabusaki”); claims 35, 36, 38, and 39 over Eggers and Holen in further view of U.S. Patent No. 5,780,234 to Meade (“Meade”); and claim 40 over Eggers, Holen, and Meade in further view of U.S. Patent No. 6,288,221 to Grinstaff (“Grinstaff”). Fundamentally, the obviousness rejections all rely on the combination of Eggers and Holen.

35 U.S.C. § 103(a) requires that “differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

matter pertains.” 35 U.S.C. § 103(a). The establishment of a *prima facie* case requires that 1) the prior art combined with general knowledge must include a suggestion or incentive to modify or combine the references; and 2) the modification or combination must have a reasonable chance of success. The Examiner has failed to provide the requisite *prima facie* case for obviousness.

As currently amended, claim 24 requires “detecting current as an indication of the presence” of a label. Neither reference provide a suggestion or the motivation to modify their teachings to reach this requirement. Eggers detects the presence of target DNA by measuring a frequency dependent effect or dielectric dispersion (Col. 5 lines 54 through Column 7 line 58). Specifically, Eggers discloses that dielectric characterization is “primarily made by measuring the dielectric constant, or equivalently, relative permittivity ϵ .” (Col. 5 lines 61-65). In addition, Eggers describes

Utilizing a four-terminal parallel plate test fixture, the electrical properties of DNA in a low concentration aqueous solution can be obtained. Four-terminal fixtures are typically used in dielectric measurements to minimize unwanted residual factors arising from self and/or mutual induction between the leads. Graphs of DNA dielectric dispersion represented by ϵ' and ϵ'' are well known and are described in greater detail in Takashima, S., J. Mol. Biol. 7:455-467 (1963), which is incorporated by reference herein. The dispersion arises from the negatively charged phosphate groups assembled in the backbone of the DNA molecule which attract the counter-ions in the solution. Although the DNA has no helix dipole moment (since it is a simple linear polyphosphate), a large dipole is induced from the counter ions in the solution being reoriented along the DNA backbone under the influence of an applied electric field. The dispersion, and hence relaxation frequency, is dependent upon the ion mobility, permittivity of the surrounding ionic medium, and the length of the DNA according to

$$f_r = (2\mu zq)^2 / \pi\epsilon / L^2 \quad [(1)]$$

where:

L is the effective molecular length of the DNA

q is the electron charge

μ is the counter-ion surface mobility,

z is the number of ions in the surrounding ionic solution,

and

ϵ is the effective permittivity of the surrounding ionic solution of z ions.

[Col. 6 line 52 through Col. 7 line 14]

As such, Eggers provides no suggestion or motivation to modify its frequency dependent effect/dielectric dispersion measurement approach to detect current. Holen likewise provides no suggestion or motivation to modify its teachings to detect current because it relies on optical

detection, not current detection. Specifically, the rotational system of Holen detects compounds in the system by using an optical reader that:

emits a beam of optical radiation onto a small portion of the test site ... [T]he optical detector converts the intensity of the optical radiation reflected by the diffuse surface of the test site into the electrical signal. The signal is then processed to obtain the optical density value of the test site 84 which is directly related to the concentration of the binding component of interest in the biological sample.

[Col. 8 lines 21-29]

As such, neither Eggers nor Holen provide a suggestion or the motivation to modify its teachings to reach the present invention.

Moreover, even if modified the references provide no reasonable expectation of success to practice the present invention. As previously discussed, Eggers utilizes Equation 1 above to calculate relaxation frequency as an indicator of the presence of a DNA target. Current is not one of the variables in the equation. As such, the modification of Eggers to detect current has no reasonable expectation of success. Holen relies on the detection of optical radiation as an indicator of the binding of a component of interest to an isolated test sites in one of its cartridges. As Holen detects optical energy and not current, the modification of the reference to detect current has no reasonable expectation of success.

With regard to claim 32, Yabusaki does not cure the defects of Eggers and Holen. With regard to claims 35, 36, 38 and 39, Meade does not cure the defects of Eggers and Holen. With regard to claim 40, Grinstaff does not cure the defects of Eggers and Holen. As such, a combination of Holen and Eggers with one of these references is insufficient to render the present invention obvious.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness and request that the various rejections under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

The present application is therefore in condition for allowance. Early and favorable notification thereof is respectfully requested. If the Examiner believes there are further unresolved issues, the Examiner is invited to call the undersigned at (415) 781-1989.

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